Message

From: Faeth, Lisa [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=12AF792B39CC4B4FA8089976F3F8859F-LFAETH]
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Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

Chemical Makers Worry Steep New EPA Fees Could Stifle Innovation

Posted: Mar 28, 2018, 7:29 AM EDT

By Adam Allington

Chemical manufacturers are concerned that hefty new EPA fees to support premarket reviews could stifle innovation and pose a barrier to bringing new chemicals to market.

A proposal would empower EPA to collect increased fees from chemical manufacturers and processors starting Oct. 1. The fees will allow the EPA to offset about $20 million in annual costs for implementing certain sections of the revised Toxic Substances Control Act.

EPA Administrator Scott Pruitt, in a February news release announcing the statement, said the proposed fee changes would ensure that the agency has "sufficient resources to review chemicals for safety with the highest scientific standards."

But chemical makers worry the fees could discourage innovation, particularly for developing new chemicals.

"Notifications for new chemicals in TSCA usually don't have a market yet, so many companies won't be able to afford the fees EPA is talking about," said Martha Marrapese, a partner with Wiley Rein, a Washington-based law firm specializing in chemical regulation.

"There will be a significant impact on innovation if they don't keep fees as low as possible," Marrapese told Bloomberg Environment. "If it costs thousands of dollars in fees, and EPA can't review applications in timely way...companies won't register their chemical here, they'll go somewhere else to do it."

Sticker Shock

The original TSCA capped fees for premanufacture notices (PMN) at $100 for small businesses and $2,500 for larger companies generating about $1.1 million annually. According to both industry and regulatory experts, there was general acknowledgment that the old levels—set three decades ago and never adjusted for inflation—needed to be substantially increased.

The new numbers on the table propose charging companies $16,000 for each premanufacture notice, new use notice, or microbial commercial activity notice.

"It is a sticker shock—to go from $2,500 to $16,000 for each PMN," said Rose Passarella, a senior scientific regulatory manager for Intertek, a Washington-based consultancy.

Another area of concern is the $4,700 the EPA is now proposing to evaluate requests for exemptions such as low-volume or test marketing exemptions.

"We have a number of serious concerns regarding the proposal," said Robert Helminiak, vice president of legal and government relations for the Society of Chemical Manufacturers and Affiliates, who's members include companies like Janssen Pharmaceuticals and BASF.

With exemptions, the EPA is applying substantial fees in an activity that has not historically had any assessment at all, and does not account for the market disruption it would cause, Helminiak said.

"EPA should not assess fees for processing these applications," he told Bloomberg Environment. "EPA should instead include the costs of reviewing exemption applications in the aggregate overhead costs of administering TSCA."

The Dow Chemical Co., PPG Industries Inc., and other companies contacted by Bloomberg Environment elected to defer comments about the new fees to their primary trade organization, the American Chemistry Council. That organization opted to withhold specific comments on the proposed fee structure until the end of the public comment period on April 27, according to an ACC spokesman.

PRIA Comparisons Not Accurate

The EPA already charges industry fees for pesticide registrations. But Marrapese of Wiley Rein said there are differences between the fees being discussed under TSCA and the ones collected under the Pesticide Registration Improvement Act of 2007 (PRIA).

"Pesticides are typically subject to a proprietary license, so companies are willing to invest more to pay for registrations," Marrapese said.

Marrapese notes that a substantial amount of scientific data and information are required to support the registration of a pesticide. These data can be very costly to create, which is why Congress included provisions in PRIA that provide certain rights to the data submitter. TSCA however, contains no provisions for data compensation.

"Under TSCA, once a new chemical goes onto the inventory, anyone can make it," she said.

High Enough?

EPA estimates the annual costs of carrying out testing on new and existing chemicals to be $80.2 million.

The agency also plans to collect fees to recover a portion of costs incurred it incurred from conducting chemical risk evaluations that manufacturers requested. The EPA expects the fee amount will range between $1.3 and $2.6 million per chemical.

But some said the proposed fees are not high enough—especially considering the greater scrutiny the new law requires the EPA to give new chemicals.

"Historically, the great majority of PMNs received by EPA never go on to be commercialized," said Richard Denison, lead senior scientist at the nonprofit Environmental Defense Fund.

According to EPA statistics, Denison said that of 40,000 PMNs reviewed over several decades, only about 14,000 went on to be commercialized, of which, only 5,300—or 13 percent—were subject to any kind of regulation or withdrawn by the submitter.

"This means that the great majority of PMNs were submitted with no meaningful intent by their manufacturers to commercialize them," he told Bloomberg Environment.

"This is not about innovation. In most cases, the decision not to commercialize a chemical had nothing to do with EPA's decision about it—meaning, almost two-thirds of the time, EPA had to waste public resources reviewing new chemicals that companies had no intent to commercialize," Denison said.

Focus on Exemptions

EPA officials have previously agreed with broad concern that higher fees for new chemical reviews "could create an economic barrier to innovation."

Because of that, the agency proposed a two-tier fee structure under which small businesses would pay about 80 percent less. But the definition of "small business" could change, based on criteria such as annual sales.

"More than ever, I expect you'll start to see a growing premium on TSCA exemptions," said Tom Berger, a partner with law firm Keller & Heckman LLP.

Companies could attempt to "consolidate exemptions" for things like test market R&D, or exemptions for low production volume chemicals, Berger said. "I think companies are going to start putting a lot more money into R&D, trying to get as much exemption as they possibly can," before they decide to file with EPA.

Chemical makers could soften some of the sticker shock by filing more consolidated premanufacture notices, Berger said during a March 14 webinar on fees that Keller & Heckman held.

In some cases, companies can consolidate up to six new, similar chemicals on an individual PMN, the EPA's proposed fee rule said, and he urged companies to contact the agency to make sure their chemicals meet the law's criteria for consolidation.

—With assistance from Pat Rizzuto.

Sticker Shock' on Proposed EPA Fees • German Efficiency • Raw Feelings About Raw Data

Posted: Mar 28, 2018, 6:46 AM EDT

By Chuck McCutcheon

The EPA wants to start collecting more fees from chemical manufacturers and processors to help pay for implementing parts of the recently revised toxic-chemicals law.

Those companies aren't buying the idea.

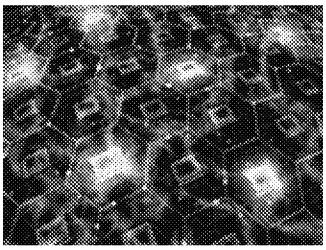
EPA Administrator Scott Pruitt said the proposal to collect "user fees" will help ensure the agency can review chemicals for safety "with the highest scientific standards," Adam Allington explains in a story being published today.

But chemical makers worry that the fees—which would be hiked from $2,500 to $16,000 in some cases—amount to "sticker shock" and could discourage innovation. Many companies won't be able to afford them, they say.

GERMANY'S BUILDINGS: Germany is trying hard to reduce greenhouse gas emissions over the next few years. But its new coalition government is looking too much at efficiency standards for new construction and not existing buildings, housing specialists tell Jabeen Bhatti in a story published today.

German cities are chock-full of older housing, ranging from prewar walk-ups to postwar reconstructed buildings. While coveted for their aesthetic appeal, many buildings still rely on antiquated heating methods and need energy-efficient renovations. Twenty percent of the country's total greenhouse gas emissions come from the nation's building sector, and 70 percent of housing stock doesn't meet current energy standards. Less than 1 percent of the needed renovations for carbon dioxide reduction have taken place.

Pruitt's Open Data Plan Could Limit Usable Research, Critics Say



EPA head Scott Pruitt's plan to ban the agency from using private or confidential data in making policy decisions would eliminate most of the scientific literature the agency reviews, scientists told Bloomberg Environment.

Washington to Be First State to Ban Firefighting Foam Chemical

Washington will be the first state to ban certain toxic chemicals in firefighting foams linked to a range of health problems when Gov. Jay Inslee (D) signs the ban into law late March 27.

INSIDEEPA.COM ARTICLES

IG Sees Uptick In Congress' Queries Into Pruitt But Budget Limits Work

EPA's Inspector General (IG) is seeing a noticeable increase in lawmakers' requests to investigate Administrator Scott Pruitt's controversial travel, security and other expenditures, but the IG says that Trump administration budget cuts, which have forced a reorganization, limit the number of such discretionary and other reviews the office can perform.

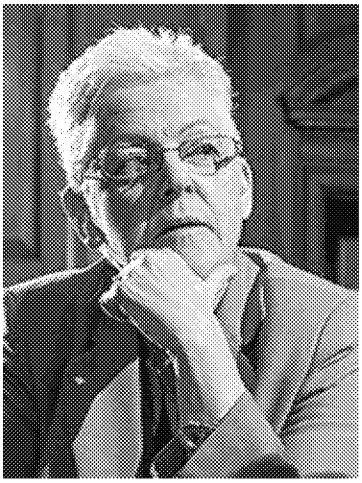
GREENWIRE ARTICLES

McCarthy, McCabe blast Pruitt's attack on 'secret science'

Maxine Joselow, E&E News

Published: Tuesday, March 27, 2018

Two former U.S. EPA officials under President Obama blasted Administrator Scott Pruitt's attack on "secret science" in a *New York Times* op-ed yesterday.



Former U.S. EPA Administrator Gina McCarthy. U.S. EPA/Flickr

Former EPA Administrator Gina McCarthy and Janet McCabe, who was acting assistant administrator of the agency's Office of Air and Radiation, sought to defend the agency's use of scientific studies when crafting regulations.

In a closed-door meeting at the Heritage Foundation earlier this month, Pruitt announced plans to restrict EPA's use of science in rulemakings (Climatewire, March 16).

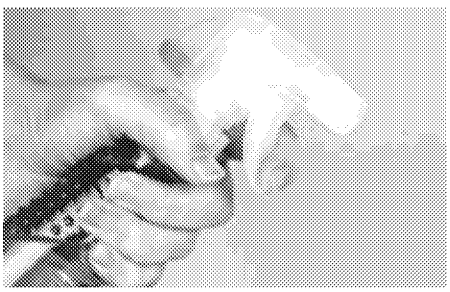
https://www.eenews.net/greenwire/2018/03/27/stories/1060077537

CHEMICAL WATCH ARTICLES

European biocides authorities agree how EDC criteria will work in practice

Papers finally adopted, criteria implemented in June

27 March 2018 / Biocides, EDCs, Europe



EU authorities have decided how the criteria for identifying endocrine disrupting chemicals will be realised in the approval processes for biocidal substances and products.

This month's meeting of the biocides competent authorities (CAs) adopted two papers after months of discussion. The endocrine disruptor criteria for biocides will begin to take effect in less than three months, on 7 June.

The criteria should have little effect on substances with an assessment report submitted before 1 September 2013. These still fall under the rules of the biocidal products Directive (BPD).

But substances with an assessment report submitted after 1 September 2013 – when the biocidal products Regulation (BPR) entered into effect – will no longer be approved, if the new criteria identify them as endocrine disrupting.

The final paper on biocidal products introduces a controversial provision: the criteria will be applied to both biocidal active and non-active substances (co-formulants) in pending product authorisation applications. This rule was met with criticism from industry, legal experts and Echa, last year.

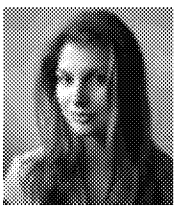
Guidance

Both the substance and product approval processes will depend greatly on the data requirements for assessing endocrine disrupting properties. Echa and the European Food Safety Authority (Efsa) are currently developing a guidance paper that will determine these. A draft of the paper was met with mixed reactions earlier this year.

Echa and Efsa's main biocides and pesticides working groups will be consulted, before publication of the final version. The biocides competent authorities and the Standing Committee on Plants, Animals, Food and Feed will also discuss it.

But Echa told the biocides CAs at this month's meeting that it is "on track" to publish the final guidance in time for June.

More detail on this story, and copies of the two CA meeting papers, are available on CW+BiocidesHub.



Vanessa Zainzinger

Biocides editor

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- EU authorities discuss EDC criteria effects on substance assessments
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- Echa predicts evaluation delays due to EDC criteria
- EDC criteria guidance consultation ends with criticism from industry, NGOs
- EU authorities agree how EDC criteria will work in practice

EU ombudsman tells Commission to share cosmetics nano information

Official sides with NGO on catalogue notifications access

27 March 2018 / Cosmetic products Regulation, Data, Europe, Nanomaterials, Personal care

The EU Ombudsman has found the European Commission guilty of maladministration over its handling of a public access request to information pertaining to the cosmetics nano inventory.

Ombudsman Emily O'Reilly has recommended that the Commission grants NGO ClientEarth access to notifications made by cosmetics manufacturers, following a complaint made a month after the inventory was published in June last year.

Specifically, she says, the EU executive should provide them with the list of all Article 16 notifications uploaded to the cosmetic products notification portal (CPNP), redacting only those parts that are covered by an exception to access provided by law.

The Commision should also ask the NGO if it wants a sample of Article 13 notifications, she added. It has until 15 June to send its opinion on the matter.

Catalogue delay

Under the cosmetics products Regulation, the Commission had been legally required to publish a catalogue, containing the details of nanomaterials present in cosmetic products by January 2014. But this was delayed by more than three years. The EU executive put it down to poor quality notifications and the need to liaise with member states and stakeholders to jointly improve the submitted data prior to publication.

In 2016 ClientEarth asked for access to the information sent by cosmetic companies to the Commission and to the draft catalogue.

In her recommendation – published this month – the Ombudsman says she was "not convinced" by the Commission's argument, at the time of the 2016 request, that the catalogue was not completed and there were only draft internal versions. It was "neither citizen friendly, nor in line with the EU public access rules", she adds.

Some of the notifications "could in fact have been extracted from the Commission's database", Ms O'Reilly says.

Although the final version of the catalogue was not published when ClientEarth originally requested access, the Ombudsman says, the Commission "failed to consult the complainant as to whether it would want access to any of the existing draft versions. This constituted maladministration."

'Useless' catalogue

Despite the long delay to publication, ClientEarth says the catalogue still does not let people identify which cosmetics contain potentially harmful nanomaterials, or assess the threat they may pose to human health.

ClientEarth lawyer Alice Bernard says consumers need to be informed so that they can "decide for themselves" whether to use products containing them.

"Sadly, the nanomaterial catalogue finally published by the Commission is useless for consumers, since it does not identify which products contain the nanomaterials. This is not in line with the cosmetics Regulation," she says.

Notifications

ClientEarth had asked for public access to information under Article 16(10)(a) of the cosmetics Regulation or, if such a catalogue did not yet exist, to notifications under Article 13(1) for cosmetics including nanomaterials, as well as the information notified under Article 16(3).

- Article 16(10)(a) says that by 11 January 2014, the Commission had to make the inventory publicly available;
- Article 13(1) requires details, such as the category of cosmetic product and name; and
- under Article 16(3) cosmetics products containing nanomaterials shall be notified to the Commission, six months prior to being placed on the market, except where they have already been placed on the market before 11 January 2013. It also sets out a series of information requirements.

Related Articles

- Commission publishes cosmetics nano inventory
- ClientEarth files complaint over EU cosmetics nano inventory

Further Information:

- Ombudsman recommendation
- ClientEarth press release
- Cosmetics Regulation

OTHER ARTICLES

Toxic turf – how great are the health risks of Switzerland's synthetic sports pitches?

Le News

The Swiss Football Association (ASF) told RTS that a ban would be disproportionate, referring to a study published in 2017 by Switzerland's Federal Office of Public Health (FOPH), which stated that an evaluation of european **and** american scientific studies done between 2004 **and** 2015 allow us to ...